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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/767,581

01/29/2004

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EXAMINER

SACKEY, EBENEZER O

ART UNIT

PAPER NUMBER

1624

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/767,581	JILANI, JAMAL A.	
	Examiner	Art Unit	
	EBENEZER SACKY	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>01/29/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This is in response to applicant's amendment filed on 01/16/07.

Status of the Claims

Claims 1-15 are pending.

Information Disclosure Statement

Receipt of the Information Disclosure Statement filed on 01/29/04 is acknowledged and has been entered into the file. A signed copy of the 1449 is attached herewith.

Response to Restriction

Applicant's election of Group I, claims 1-15 (in part) in the reply filed on 01/16/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for other forms, does not reasonably provide enablement for the use of NSAID's broadly. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make diverse derivatives of NSAID's and to use same prophylactically commensurate in scope with these claims. The claims, insofar as they embrace all NSAID's are not

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enabled. NSAID and *in vivo* are generic. The type of NSAID recommended will usually depend on a number of factors, such as the patient diagnosis, clinical situation and level of pain. For example most episodes of back pain have inflammation as a contributing factor, anti-inflammatory medication such as NSAID's are often an effective treatment. However, NSAID's comprise a large class of drugs with many different options. In addition to aspirin, there are currently several types of both non-prescription and prescription brands.

The evidence in the specification is clear: the disclosure does not provide evidence that all NSAID's possess the properties needed for providing a patient suffering from a condition treatable by the administration of any NSAID and there is no evidence that such compounds have been used to prevent or treat any disease caused by the use of compounds of claim 1.

The claims are drawn to the use of NSAID's. The examples presented in the specification are limited to morpholinocarbonyloxy ethyl ester compounds. These asserted products couldn't be simply willed into existence. As stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ 2d 1190 "the specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However, there is no evidence that such compounds exist..... the examples of the '881' patent do not produce the postulated compounds.....there isno evidence that such compounds even exist." The same circumstance appears to be true here: there is no evidence that all NSAID's are actually applicable. Hence, applicants must now show that all NSAID's can be made and used

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in the methods claimed, or limit the claims to using those products for which there is full, clear and exact support. With regard to prodrug forms, there is no guidance as to the structural makeup of such, and is completely unknown as well as the point of attachment to the remainder of the basic structure. In the absence of any intended property that requires modification of the parent drug, it would not be routine to determine the intended scope. Furthermore, it is not the norm that one can predict with any degree of accuracy that a particular prodrug form of an active compound will be more soluble, more easily handled in formulations or more bioavailable without actual *in vivo* testing.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for morpholinocarbonyloxyethyl ester species, does not reasonably provide enablement for all NSAID's. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. From a reading of the specification, the scope of disorders includes but not limited to pain, fever and inflammation, as the scope includes **all inflammatory conditions**,

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which includes various disorders very difficult to treat. The notion that a morpholinocarbonyloxyethyl ester compounds, have such a range of uses is not seen in the art at the time of applicants' effective filing or even in the present. While NSAID compounds have unique properties as anti-inflammatory agents, and thus, for treating specific inflammatory diseases, there is no evidence of record that there is a correlation of success for the remaining disclosed diseases covered by the instant claims (i.e., various disorders associated with NSAID's). The lists of diseases constitute "an invitation to experiment" which is not in compliance with 35 USC 112. See Wolfe et al., Gastrointestinal Toxicity of Nonsteroidal Antiinflammatory Drugs; The New England Journal Of Medicine, (June 17, 1999) and its role in response to NSAID mediated diseases. Applicants provide no scientific data in the specification to controvert the findings in the art from which one can reasonably conclude that all of applicants' compounds possess all these uses. Where the assertion of utility is unusual, difficult to treat or speculative, the Examiner has the authority to require evidence that tests relied on are reasonably predictive of *in vivo* efficacy by those skilled in the art. See for example, *In re Ruskin*, 148 USPQ 221, *Ex parte Jovanovics*, 211 USPQ 907. Note MPEP 2164.05(a).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claims 1-15 are of indeterminate scope because such claim language (providing a patient suffering from a condition treatable by the administration of an NSAID) which relies on a mode of action or underlying cause renders the scope of the claims indeterminate as the claim language may read on diseases or disorders not yet understood or known to be caused by or affected by such action or in ways not yet understood. One of ordinary skill in the art would not be apprised of the scope of diseases to be treated by administering the current compounds. Under such conditions how can one determine if any use not disclosed by applicants infringes or not.

2. The formula in claim 1, does not appear to embrace the morpholino species made in the examples. The correct formula should be $RC(O)O\text{-}spacer\text{-}OC(O)R'$.
clarification is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (571) 272-0704. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for this Group is (571) 273-8300.

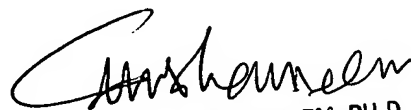
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

EOS

March 8, 2007



James O. Wilson
Supervisory Patent Examiner
Art Unit 1624, Group 1600
Technology Center 1



GOLAM M. M. SHAMEEM, PH.D
PRIMARY EXAMINER